Vaxcyte and Lonza Expand Collaboration for Global Commercial Manufacturing of Broad-Spectrum Pneumococcal Conjugate Vaccines (PCVs)

October 16, 2023

-- New Agreement to Establish Global Commercial Manufacturing Capacity for Vaxcyte's PCV Candidates, VAX-24 and VAX-31, in Adult and Pediatric Populations --

-- Expanded Collaboration Builds on Vaxcyte's Current Strategy to Conduct Initial Commercial Launch of VAX-24 in Adults from Existing Lonza Facilities in Visp (CH) --

-- Long-Standing Relationship Between the Companies Further Enhanced as Vaxcyte Progresses Lead Vaccine Candidate into Late-Stage Clinical Development --

-- New Purpose-Built Large-Scale Manufacturing Suite in Lonza's Ibex ® Dedicate Biopark --

SAN CARLOS, Calif. and BASEL, Switzerland, Oct. 16, 2023 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases, and Lonza, a global manufacturing partner to the pharmaceutical, biotech and nutraceutical markets, today announced the companies have entered into a new commercial manufacturing agreement. Expanding on their existing collaboration, this agreement supports the potential global commercialization of Vaxcyte's PCV candidates, VAX-24 and VAX-31, in both the adult and pediatric populations. This agreement complements Vaxcyte's plans to utilize existing Lonza infrastructure to advance clinical development and the anticipated initial U.S. launch of VAX-24 for the adult population.

Under the terms of the agreement, Lonza will provide Vaxcyte with a custom-built manufacturing suite as part of Lonza's Ibex ® Dedicate Biopark at its Visp (CH) site to manufacture key components, including drug substances, for Vaxcyte's PCV franchise. Beginning with VAX-24, which is moving into late-stage clinical development, Vaxcyte's dedicated manufacturing suite is expected to meet the potential long-term market demand for both the adult and pediatric populations globally. The design of the dedicated manufacturing suite is nearly complete, with equipment installation expected to begin in 2024. Lonza is anticipated to create up to 300 new jobs upon reaching peak capacity.

"Following the successful completion of our VAX-24 Phase 2 adult studies, and as we prepare for Phase 3 clinical studies, we are excited to expand our relationship with Lonza, a preeminent contract development and manufacturing organization, and put into motion the key steps required to establish large-scale and long-term commercial manufacturing capacity for our PCV candidates," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "This outcome is consistent with our strategic objectives and financial plan. We expect this dedicated manufacturing suite within Lonza's Ibex ® facility will enable us to scale up effectively to meet the potential supply demands for VAX-24, followed by VAX-31, our 31-valent PCV, across all populations and on a global scale."

Over the past year, Vaxcyte has made significant progress with its VAX-24 clinical program, reporting positive results for two Phase 2 studies in adults and initiating a Phase 2 study in infants. The positive data from the VAX-24 adult Phase 2 clinical program support a potential best-in-class profile for Vaxcyte's 24-valent PCV candidate by virtue of its broader coverage and improved immune responses compared to the standard-of-care. VAX-24 was designed to address an important public health need by expanding coverage beyond the standard-of-care and including the serotypes that are responsible for a significant portion of invasive pneumococcal disease (IPD) currently in circulation in both infants and adults.

"Our expanded relationship with Vaxcyte highlights the value of our services on the path towards commercialization," said Jean-Christophe Hyvert, President, Biologics Division at Lonza. "Having supported the early-stage clinical development of Vaxcyte's PCV programs, we are pleased to continue our long-standing collaboration by supporting the late-stage clinical manufacturing utilizing our unique Ibex® Dedicate offering, with the capability to provide commercial supply of their products."

About Vaxcyte
Vaxcyte is a vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. The Company is developing broad-spectrum conjugate and novel protein vaccines to prevent or treat bacterial infectious diseases. Vaxcyte's lead candidate, VAX-24, is a 24-valent, broad-spectrum, carrier-sparing PCV being developed for the prevention of IPD and is poised to move into late-stage development. VAX-31, the only 31-valent PCV in development, is a follow-on candidate to VAX-24 and part of the Company's PCV franchise.

Vaxcyte is re-engineering the way highly complex vaccines are made through modern synthetic techniques, including advanced chemistry and the XpressCF™ cell-free protein synthesis platform, exclusively licensed from Sutro Biopharma, Inc. Unlike conventional cell-based approaches, the Company's system for producing difficult-to-make proteins and antigens is intended to accelerate its ability to efficiently create and deliver high-fidelity vaccines with enhanced immunological benefits. Vaxcyte's pipeline also includes VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease; and VAX-GI, a vaccine program designed to prevent Shigella. Vaxcyte is driven to eradicate or treat invasive bacterial infections, which have serious and costly health consequences when left unchecked.
For more information, visit www.vaxcyte.com.

About Pneumococcal Disease
Pneumococcal disease (PD) is an infection caused by Streptococcus pneumoniae (pneumococcus) bacteria. It can result in IPD, including meningitis and bacteremia, and non-invasive PD, including pneumonia, otitis media and sinusitis. In the United States, approximately 320,000 people get pneumococcal pneumonia each year, which is estimated to result in approximately 150,000 hospitalizations and 5,000 deaths. Pneumococci also cause over 50% of all cases of bacterial meningitis in the United States. Antibiotics are used to treat PD, but some strains of the bacteria have developed resistance to treatments. The morbidity and mortality due to PD are significant, particularly for young children and older adults, underscoring the need for a more broad-spectrum vaccine.

About Lonza
Lonza is a preferred global partner to the pharmaceutical, biotech and nutrition markets. We work to enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence. Our unparalleled breadth of offerings enables our customers to commercialize their discoveries and innovations in the healthcare industry.

Founded in 1897 in the Swiss Alps, today, Lonza operates across five continents. With approximately 17,500 full-time employees, we comprise high-performing teams and individual talent who make a meaningful difference to our own business, as well as to the communities in which we operate. The company generated sales of CHF 3.1 billion with a CORE EBITDA of CHF 922 million in Half-Year 2023. Find out more at www.lonza.com

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Vaxcyte Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements related to the potential benefits of VAX-24 and VAX-31, including breadth of coverage, the ability to deliver a potentially best-in-class profile, the ability to deliver potentially better immune responses and the improvement upon the standard-of-care; the anticipated timing of clinical developments for VAX-24 and VAX-31; the ability to add more pneumococcal strains to VAX-24 and VAX-31 without compromising the overall immune response; the potential of VAX-31 to serve as a follow-on candidate to VAX-24; the ability of Vaxcyte to commercialize VAX-24 and VAX-31; the timing and strategy regarding the initial commercial launch of VAX-24; the potential market demand for VAX-24 and VAX-31; the ability of Vaxcyte's dedicated manufacturing suite to meet the potential long-term market demand for both the adult and pediatric populations globally; the timing and plans regarding the build out of the dedicated manufacturing suite; Vaxcyte's ability to establish large-scale and long-term commercial manufacturing capacity for its PCV candidates; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "potential," "should," "would" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on Vaxcyte's current expectations and actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, including, without limitation, risks related to Vaxcyte's product development programs, including development timelines, success and timing of chemistry, manufacturing and controls and related manufacturing activities, potential delays or inability to obtain and maintain required regulatory approvals for its vaccine candidates, and the risks and uncertainties inherent with preclinical and clinical development processes; the success, cost and timing of all development activities and clinical trials; each Company's ability to fund development activities and achieve development goals; and each Company's ability to protect intellectual property. These and other risks are described more fully in Vaxcyte's filings with the Securities and Exchange Commission (SEC), including, without limitation, its Quarterly Report on Form 10-Q filed with the SEC on August 8, 2023 or in other documents Vaxcyte subsequently files with or furnishes to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date, and readers should not rely upon the information in this press release as current or accurate after its publication date. Vaxcyte undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations. Readers should not rely upon the information in this press release as current or accurate after its publication date.

Additional Information and Disclaimer of Lonza
Lonza Group Ltd has its headquarters in Basel, Switzerland, and is listed on the SIX Swiss Exchange. It has a secondary listing on the Singapore Exchange Securities Trading Limited ("SGX-ST"). Lonza Group Ltd is not subject to the SGX-ST's continuing listing requirements but remains subject to Rules 217 and 751 of the SGX-ST Listing Manual.

Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.

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